IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS
BOSTON DIVISION

UNITED STATES OF AMERICA	§	
ex rel. James Banigan and Richard Templin	§	
	§	
STATE OF CALIFORNIA, *ex rel.*	§	
James Banigan and Richard Templin;	§	
STATE OF DELAWARE, *ex rel.*	§	
James Banigan and Richard Templin;	§	
DISTRICT OF COLUMBIA *ex rel.*	§	
James Banigan and Richard Templin;	§	
STATE OF FLORIDA *ex rel.*	§	CIVIL NO. 07-12153-RWZ
James Banigan and Richard Templin;	§	
STATE OF GEORGIA *ex rel.*	§	
James Banigan and Richard Templin;	§	
STATE OF HAWAII *ex rel.*	§	
James Banigan and Richard Templin;	§	
STATE OF ILLINOIS *ex rel.*	§	
James Banigan and Richard Templin;	§	
STATE OF INDIANA *ex rel.*	§	
James Banigan and Richard Templin;	§	**FILED IN CAMERA AND**
STATE OF LOUISIANA *ex rel.*	§	**UNDER SEAL**
James Banigan and Richard Templin;	§	
COMMONWEALTH OF MASSACHUSETTS	§	
ex rel. James Banigan and Richard Templin;	§	
STATE OF MICHIGAN *ex rel.*	§	
James Banigan and Richard Templin;	§	
STATE OF MONTANA *ex rel.*	§	
James Banigan and Richard Templin;	§	
STATE OF NEVADA *ex rel.*	§	
James Banigan and Richard Templin;	§	
STATE OF NEW HAMPSHIRE *ex rel.*	§	
James Banigan and Richard Templin;	§	
STATE OF NEW MEXICO *ex rel.*	§	JURY TRIAL DEMANDED
James Banigan and Richard Templin;	§	
STATE OF NEW YORK *ex rel.*	§	
James Banigan and Richard Templin;	§	
STATE OF OKLAHOMA *ex rel.*	§	
James Banigan and Richard Templin;	§	
STATE OF TENNESSEE *ex rel.*	§	
James Banigan and Richard Templin;	§	

STATE OF TEXAS *ex rel.* James Banigan and Richard Templin; COMMONWEALTH OF VIRGINIA *ex rel.* James Banigan and Richard Templin; STATE OF NEW JERSEY *ex rel.* James Banigan and Richard Templin; STATE OF RHODE ISLAND *ex rel.* James Banigan and Richard Templin;	§
Plaintiffs,	§
VS.	§
ORGANON USA INC.; OMNICARE, INC.; PHARMERICA, INC.; ORGANON BIOSCIENCES N.V.; SCHERING PLOUGH CORP; and AKZO NOBEL N.V.	§
Defendants.	§

FIRST AMENDED COMPLAINT OF RELATORS JAMES BANIGAN AND RICHARD TEMPLIN PURSUANT TO FEDERAL FALSE CLAIMS ACT, AND VARIOUS STATE FALSE CLAIMS ACTS

1. The United States of America, the States of California, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Michigan, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, Oklahoma, Rhode Island, Tennessee and Texas, the Commonwealths of Massachusetts and Virginia, and the District of Columbia, by and through *qui tam* relators James Banigan and Richard Templin, bring this action under 31 U.S.C. §§ 3729–3732 (the "False Claims Act") to recover all damages, penalties and other remedies established by the False Claims Act on behalf of the United States and themselves and would show the following:

I. PARTIES

2. Relator James Banigan is a citizen of the United States and a resident of the State of New Jersey.

3. Relator Richard Templin is a citizen of the United States and a resident of the State of New Jersey.

4. Defendant Akzo Nobel is a Netherlands corporation specializing in chemical coatings. Akzo Nobel conducts extensive business in the States of California, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Michigan, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, Oklahoma, Rhode Island, Tennessee and Texas, the Commonwealths of Massachusetts and Virginia, and the District of Columbia. Akzo Nobel may be served through its registered agent, Akzo Nobel, 7 Livingston Ave., Dobbs Ferry, NY 10522.

5. Defendant Organon USA, Inc. was a New Jersey corporation whose principal business was the development, manufacture, and sale of health care products and services, including pharmaceuticals. Organon USA, Inc.'s principal place of business was at 2000 Galloping Hill Road, Kenilworth, New Jersey 07033-0530. Organon USA, Inc. conducted extensive business in the States of California, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Michigan, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, Oklahoma, Rhode Island, Tennessee and Texas, the Commonwealths of Massachusetts and Virginia, and the District of Columbia. Organon USA, Inc. was wholly owned by Organon BioSciences N.V., which was in turn wholly owned by Akzo Nobel, a Netherlands corporation specializing in chemical coatings. Organon USA, Inc. manufactured and sold prescription drugs that are paid for by state Medicaid programs, including such medications as Remeron Tablet and Remeron SolTab. Akzo Nobel announced on March 12,

2007 its intent to sell Organon Biosciences N.V. to pharmaceutical company Schering-Plough for EUR 11 billion ($14.4 billion based on the closing exchange rate on March 9, 2007). Schering-Plough finalized its acquisition of Organon BioSciences N.V. in November 2007, and Organon Biosciences N.V. became a subsidiary of Schering Plough. Organon USA, Inc. may be served through its registered agent, Akzo Nobel, 7 Livingston Ave., Dobbs Ferry, NY 10522.

6. Defendant Organon Biosciences N.V. was a Netherlands corporation specializing in the development, manufacture, and sale of human and animal health care products and services, including pharmaceuticals. Organon Biosciences N.V. conducted extensive business in the States of California, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Michigan, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, Oklahoma, Rhode Island, Tennessee and Texas, the Commonwealths of Massachusetts and Virginia, and the District of Columbia. Organon Biosciences N.V. may be served through its registered agent, Akzo Nobel, 7 Livingston Ave., Dobbs Ferry, NY 10522.

7. Defendants Akzo Nobel, Organon USA, Inc., and Organon Biosciences N.V. are hereinafter referred to collectively as "Organon." Defendants Organon USA, Inc. and Organon Biosciences N.V. are hereinafter referred to collectively as "Organon IBS."

8. Defendant Schering-Plough is a New Jersey corporation whose principal business is the development, manufacture, and sale of health care products and services, including pharmaceuticals. Schering-Plough conducts extensive business in the States of California, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Michigan, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, Oklahoma, Rhode Island, Tennessee and Texas, the Commonwealths of Massachusetts and Virginia, and the District of Columbia.

Schering-Plough may be served through its registered agent, The Corporation Trust Company, 820 Bear Tavern Rd, West Trenton, NJ 08628.

9. Defendant Omnicare, Inc. is a Delaware corporation whose principal business is providing pharmacy services to patients in long-term care settings. Omnicare's principal place of business is 100 East RiverCenter Boulevard, Covington, Kentucky 41011. Omnicare conducts extensive business in the States of California, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Michigan, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, Oklahoma, Rhode Island, Tennessee and Texas, the Commonwealths of Massachusetts and Virginia, and the District of Columbia. Omnicare may be served through its registered agent, CSC – Lawyers Incorporating Service, 421 West Main, Frankfort, KY 40601.

10. Defendant PharMerica, Inc. is a Delaware corporation whose principal business is providing pharmacy services to patients in long-term care settings. PharMerica's principal place of business is at 1901 Campus Place, Louisville, Kentucky 40299. PharMerica conducts extensive business in the States of California, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Michigan, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, Oklahoma, Rhode Island, Tennessee and Texas, the Commonwealths of Massachusetts and Virginia, and the District of Columbia. PharMerica became a wholly-owned subsidiary of Bergen Brunswig, after which Bergen Brunswig merged with AmeriSource Health Corporation on March 29, 2001 to form AmerisourceBergen. In 2006, AmerisourceBergen merged PharMerica with Kindred Healthcare Inc. to form PharMerica Long-Term Care. PharMerica may be served through its registered agent, CSC-Lawyers Incorporating Service, 421 West Main, Frankfort, KY 40601.

II. RESPONDEAT SUPERIOR AND VICARIOUS LIABILITY

11. Any and all acts alleged herein to have been committed by the Organon defendants were committed by officers, directors, employees, representatives or agents who at all times acted on behalf of their respective Organon defendant(s) and within the course and scope of their employment.

12. The Organon defendants are related entities sharing common employees, offices and business names such that they are jointly and severally liable under legal theories of respondeat superior. Further, the past, present and continuing relations and dealings by and between these related entities are so inextricably intertwined that for purposes of this suit, some or all of them can and should be considered as a single entity at law and equity.

III. SUCCESSOR LIABILITY

13. Defendant Schering-Plough is the successor-in-interest to the Organon IBS defendants and has assumed their rights, duties, and liabilities. Schering Plough's purchase of the Organon IBS defendants has resulted in the substantial continuity of the Organon IBS defendants' business. For example, Schering Plough retained some of Organon USA, Inc.'s employees, including Carroll "Butch" McKenna, Director for Senior Care/Long Term Care for Organon USA, Inc., and now a District Manager for Schering Plough, Mike Dziomba, Vice President of Fertility for Organon USA, Inc., and now Executive Director of Sales for Schering Plough, and members of Organon USA Inc's legal counsel, Fred Figa and Jon Beck, as a result of its purchase of the Organon IBS defendants. In addition, Schering-Plough retained the Organon IBS defendants' production facilities, continued to produce the Organon IBS defendants' products, such as Remeron, and continued to use the Organon IBS defendants' name

in conjunction with the Schering-Plough name. As successor-in-interest to the Organon IBS defendants, Schering-Plough has assumed Organon's liabilities with respect to this suit.

IV. JURISDICTION AND VENUE

14. Jurisdiction and venue are proper in this Court for the following reasons:

i. Jurisdiction for this Court exists pursuant to the False Claims Act (31 U.S.C. § 3730(b) (1) and 31 U.S.C. § 3732(a)) because Relators' claims seek remedies on behalf of the United States for Defendant's multiple violations of 31 U.S.C. § 3729, some of which occurred in the Southern District of Texas and the District of Massachusetts, and because Defendant transacts other business within the Southern District of Texas and the District of Massachusetts.

ii. Venue exists in the United States District Court for the Southern District of Texas and the District of Massachusetts pursuant to 31 U.S.C. § 3730(b) (1) and 31 U.S.C. § 3732(a) because Defendant is qualified to do business in the State of Texas and the Commonwealth of Massachusetts and conducts business within the State of Texas and within the Southern District of Texas and the District of Massachusetts and Defendant transacts business or committed acts proscribed by § 3729, in the State of Texas and the Commonwealth of Massachusetts and the Southern District of Texas and the District of Massachusetts.

V. INTRODUCTION

15. This suit concerns pharmaceutical company Organon's seven-year scheme to offer unlawful enticements to long-term care pharmacies in exchange for prescribing its anti-depressants, Remeron Tablet and Remeron SolTab, to their patients, resulting in at least $348 million in wrongful Medicaid prescription reimbursement costs. Organon took advantage of the fact that nursing homes and other long-term care facilities nationwide are serviced by a handful of giant, closed-door, specialized long-term care pharmacies such as PharMerica and Omnicare. These pharmacies are uniquely able to influence or control what medications are prescribed to a

patient. Beginning in 1999 and lasting through 2005, Organon secretly offered these pharmacies and their buying groups deep discounts of up to almost 23.5% and other inducements in exchange for converting patients' prescriptions to Remeron Tablet and Remeron SolTab. All of these inducements were offered at Medicaid's expense and constituted kickbacks under federal law. In addition, Organon coupled these inducements with a nationwide off-label marketing scheme to bolster sales of Remeron Tablet and Remeron SolTab in the long-term care sector resulting in market growth and share that was up to three times higher than in the commercial business sector.

16. Following Remeron Tablet's patent expiration in 1998, Organon anticipated that generic competition, set to begin in 2001, could cause the company a catastrophic loss of profits. In the face of that threat, Organon sought approval from the Food and Drug Administration (the "FDA") for a variant form of Remeron—an orally disintegrating tablet called Remeron SolTab—that was not rated AB equivalent to Remeron Tablet, effectively barring generic competition for the variant form.

17. Organon then engaged in a fraudulent scheme with long-term care pharmacy providers and group purchasing organizations to exploit the Medicaid reimbursement system by maximizing Medicaid reimbursement to pharmacies while minimizing the price pharmacies actually paid for the drugs. Organon's average wholesale price for Remeron Tablet was already inflated, but beginning in 1999, Organon offered long-term care pharmacies deep discounts and rebates in conjunction with that price to increase the "spread" for the drug further. Upon Remeron SolTab's launch in 2001, Organon set an even higher average wholesale price for the new form and began shifting the discounts and rebates to Remeron SolTab to encourage pharmacies to convert from Remeron Tablet to the patent-protected Remeron SolTab. Organon

then conspired with long-term care providers, including Omnicare and PharMerica, as well as group purchasing organizations, by entering into long-term contracts that provided explicitly for these illegal discounts and rebates, such as ramp-up discounts, rebates, conversion rebates, and therapeutic interchange rebates. These inducements constitute illegal kickbacks under the Medicare and Medicaid Protection Act of 1987 (the "Anti-Kickback Statute"). See 42 U.S.C. § 1320a-7b.

18. Remeron's active ingredient, mirtazapine, is a noradrenergic and selective serotonergic anti-depressant. Organon's sales pitch to long-term care pharmacies simply appealed to pharmacies' "opportunity to profit" on Medicaid prescriptions. But Organon also specifically trained long-term care pharmacists and their attending clinicians to maximize conversion of residents' anti-depressant prescriptions to Remeron by promoting Remeron's short-term side effects of somnolence and weight gain as though they were indications. In essence, Organon held out the promise of a more docile, easily controlled resident population.

19. Organon's appeal to pharmacies to convert patients to Remeron Tablet and Remeron SolTab was spectacularly successful. Remeron was Organon's top selling drug from 1999 to 2005. Remeron sales from 1999 to 2004 totaled an estimated $693 million in Medicaid sales, with $347.5 million in long-term care sales.

20. Further, by engaging in this scheme to defraud Medicaid with long-term pharmacy providers, such as PharMerica and Omnicare, as well as group purchasing organizations, Organon effectively reduced its liability for Remeron Tablet and Remeron SolTab under its rebate agreement with Medicaid. When calculating its average manufacturer price, Organon included as a deduction the deep discounts offered on Remeron Tablet and Remeron SolTab to long-term care customers, even though the discounts constituted illegal kickbacks,

thus decreasing its average manufacturer price, which lowered its rebate liability to Medicaid accordingly.

21. Not only did Organon claim reductions to its rebate liability based on illegal kickbacks, but it falsely reported pricing for a number of long-term care transactions involving Remeron Tablet and Remeron SolTab, further lowering the rebate it paid to state Medicaid programs. For example, Organon on two occasions sold a high volume of Remeron SolTab to Omnicare and PharMerica at "bargain basement" prices in exchange for the simultaneous purchase of more Remeron SolTab at normal commercial prices without reporting these transactions together to Medicaid, thereby lowering the Organon's rebate liability to state Medicaid programs.

22. In addition, from 1999 to 2005, Organon intentionally or recklessly failed to maintain its membership list of 340B program "covered entities." The 340B Pricing Program allows certain non-profits and other companies to receive government pricing under the Public Health Service Act of 1992. 42 U.S.C. § 256b. Because Organon failed to employ effective procedures that would have enabled it to properly monitor its membership list of 340B covered entities, for six years Organon continually sold its drugs, including Remeron and Remeron SolTab, to customers who were not qualified to receive this special 340B pricing. Prices provided to entities not qualified to receive the 340B pricing would have affected Remeron's true "best price" to the private sector, but Organon failed to report these transactions at all, and Organon made no attempt to recoup discounts afforded to these ineligible entities. If Organon had reported these transactions, a lower best price would have resulted in a significantly higher Medicaid rebate liability.

23. In another fraudulent scheme, Organon was able to expand and maintain its market share of Remeron and Remeron SolTab by deliberately and deceptively marketing uses that had not been approved by the Food and Drug Administration ("FDA") .

24. Organon's marketing of potential profits and off-label promotions violated the False Claims Act for two reasons. First, state Medicaid programs have paid claims for reimbursement for prescriptions that were tainted by remuneration that violated the Anti-Kickback Statute. Second, these same prescriptions arose from illegal off-label promotion of Remeron and Remeron SolTab.

25. Further, Organon, PharMerica, Omnicare, and other long-term care pharmacy providers violated the False Claims Act by conspiring to obtain payment for claims submitted for reimbursement for illegally-obtained prescriptions for Remeron Tablet and Remeron SolTab.

26. Finally, Organon violated the False Claims Act by making false statements and/or records that led to a decrease in its obligation under state Medicaid rebate programs. Organon took advantage of its fraudulent, financial incentives, such as discounts and rebates, to its long-term care pharmacy provider customers to effectively lower the average manufacturer prices for Remeron Tablet and Remeron SolTab that Organon reported to Medicaid. In addition, Organon avoided disclosing its true best price for Remeron SolTab products. Further, Organon failed to maintain control of its membership list of 340B covered entities, causing ineligible entities to receive 340B pricing. Organon then failed to report these transactions as part of its best price reporting. These acts had the effect of lowering Organon's Medicaid rebate liability for Remeron Tablet, Remeron SolTab.

VI. LAW

A. The False Claims Act

27. The False Claims Act ("FCA") provides in pertinent part that:

> (a) Any person who
>
> (1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval;
> (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government;
> (3) conspires to defraud the Government by getting a false or fraudulent claim allowed or paid;
>
> ***
>
> (7) knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government,

is liable to the Government for a civil penalty of not less than $5,500 and not more than $11,000 for each such claim, plus three times the amount of damages sustained by the Government because of the false or fraudulent claim. 31 U.S.C. § 3729(a).

B. The Federal Anti-Kickback Statute

28. The Medicare-Medicaid Anti-Fraud and Abuse Amendments, known as the Medicare Anti-Kickback Statute (the "Anti-Kickback Statute"), 42 U.S.C. § 1320a-7b(b), make it illegal for an individual knowingly and willfully to offer or pay remuneration in cash or in kind to induce a physician to order a good or service that is reimbursed by a federal healthcare program. *See* 42 U.S.C. § 1320a-7b(b)(2). "Remuneration" is broadly defined to include anything of value offered or paid in return for purchasing, ordering, or recommending the purchase or order of any item reimbursable by a federal healthcare program.

29. The purpose of the Anti-Kickback Statute is to prohibit such remuneration in order to secure proper medical treatment and referrals and to limit unnecessary treatment, services, or goods that are based not on the needs of the patient but on improper incentives given to others, thereby limiting the patient's right to choose proper medical care and services.

30. Paying kickbacks taints an entire prescription, regardless of the medical propriety of its use. The kickback inherently interferes with the doctor-patient relationship and creates a conflict of interest, potentially putting the patient's health at risk.

C. The Medicaid Program

31. Medicaid was established by Title XIX of the Federal Social Security Act, 42 U.S.C. § 1396 *et seq.* (the "Medicaid Program"). Medicaid is a joint federal-state program that provides health care benefits for certain groups, primarily the poor and disabled.

32. The federal Medicaid statute sets forth the minimum requirements for state Medicaid programs to qualify for federal funding. *See* 42 U.S.C. § 1396a. The federal portion of states' Medicaid payments, known as the Federal Medical Assistance Percentage ("FMAP"), is based on a state's per capita income compared to the national average. 42 U.S.C. § 1396d(b). Among the states, the FMAP is at least 50%, and as high as 83%.

33. The vast majority of states award contracts to private companies to evaluate and process Medicaid recipients' claims for payment. Typically, after processing the claims, these private companies then generate funding requests to the state Medicaid program, which in turn obtains federal funds from the United States.

D. 340B Covered Entities

34. The Public Health Service Act of 1992 established the Section 340B drug discount program. 42 U.S.C. § 256b. Under the 340B program, drug manufacturers are required

to provide statutorily defined discounts on outpatient drugs to covered entities. "Manufacturers are required to participate in the 340B program as a condition of having drug charges reimbursed by Medicaid." *County of Santa Clara v. Astra USA, Inc.*, 2006 U.S. Dist. LEXIS 57176 (N.D. Cal. July 28, 2006.

35. "Covered entities" mean federally qualified health center look-alike programs; certain disproportionate share hospitals owned by, or under contract with, state or local governments, and several categories of facilities or programs funded by federal grant dollars, including federally qualified health centers, AIDS drug assistance programs, hemophilia treatment centers, sexually transmitted disease ("STD") grant recipients, and family planning clinics. 42 U.S.C. § 256b.

VII. OVERVIEW OF ORGANON, REMERON AND THE LONG-TERM CARE ARENA

A. Organon and Its Long-Term Care Customers

i. Organon

36. Organon USA Inc. ("Organon") was a pharmaceutical company headquartered in Roseland, New Jersey that manufactures and markets pharmaceuticals for human use. Its core therapeutic fields were reproductive medicine, contraception, anesthesia, and psychiatry. Organon was wholly owned by Organon BioSciences N.V. (OBS), which was in turn wholly owned by Akzo Nobel, a Netherland corporation specializing in chemical coatings. Akzo Nobel announced on March 12, 2007 its intent to sell OBS to pharmaceutical company Schering-Plough for EUR 11 billion ($14.4 billion based on the closing exchange rate on March 9, 2007). Schering Plough finalized its acquisition of Organon in November 2007.

ii. PharMerica

37. In 1999, PharMerica was one of the nation's largest long-term care pharmacy providers, specializing in the provision of pharmacy supplies and services to long-term care institutions. It provided pharmacy products and services to approximately 500,000 patients in long-term care and alternative settings, servicing an estimated 380,000 beds in skilled nursing facilities. On April 26, 1999, Bergen Brunswig acquired PharMerica, Inc. and PharMerica became a wholly-owned subsidiary of Bergen Brunswig. Bergen Brunswig then merged with AmeriSource Health Corporation on March 29, 2001 to form AmerisourceBergen. In 2006, AmerisourceBergen merged PharMerica with Kindred Healthcare Inc. to form PharMerica Long-Term Care, now headquartered in Louisville, Kentucky, allowing PharMerica to better compete with the nation's current giant of long-term care pharmacy services, Omnicare.

iii. Omnicare

38. From 2001 to 2005, Omnicare, headquartered in Covington, Kentucky, systematically acquired its competitor long-term care pharmacy providers, NeighborCare, NCS Healthcare, and American Pharmaceutical Services ("APS"), a subsidiary of Mariner Health Group, making it the nation's largest provider of pharmacy services to long-term care facilities, providing pharmacy services to an estimated 1,400,000 beds in long-term care facilities and other chronic care settings. Omnicare acquired American Pharmaceutical Services from Mariner in 2002, NCS Healthcare in 2003, and NeighborCare, Inc. in 2005.

B. Remeron: Regulatory History and Medical Attributes

39. Organon launched Remeron Tablet in August of 1996 following FDA approval of the drug for the treatment of depression in adults. The drug was billed as the first in a new class

of anti-depressants called "noradrenergic and selective serotonergic anti-depressants" ("NaSA"). Remeron Tablet were manufactured in 15 mg, 30 mg, and 45 mg formulations, taken once a day.

40. According to Organon's literature, Remeron has a dual-action effect that rectifies an imbalance of the brain chemicals noradrenaline and serotonin, both of which are believed to be involved in causing depression. Remeron is believed to exert its therapeutic effects by increasing the release of both of these neurotransmitters from nerve cells in the brain, thereby correcting the deficiencies and relieving depressive symptoms such as depressed mood.

41. Organon's patent for Remeron, first issued in 1977, expired on June 14, 1998, with generic manufacturers expected to enter the market as early as May 2001. Organon's managers saw the expiration of Remeron's patent as a potentially cataclysmic event for the company, likely resulting in significant layoffs. Organon undertook three actions to prevent the perceived disaster. First, on November 2, 1999, Organon obtained a new patent that purported to claim a combination therapy of mirtazapine together with a selective serotonin reuptake inhibitor ("SSRI"), which effectively blocked generic competitors' entry to the marketplace until February of 2003. A patent infringement suit and a related case against Organon brought by generic manufacturers ensued, with the latter case finally settling in August of 2005.

42. Second, Organon submitted a new drug application to the FDA for a variant form of Remeron: an orally disintegrating tablet called Remeron SolTab, available in the same dosages as the tablets. Organon trumpeted Remeron SolTab as improving "patient compliance," particularly in long-term care, because it could be administered without water. The FDA approved the new Remeron product on January 12, 2001. Because Remeron SolTab was not initially rated as AB equivalent to Remeron Tablet, generic competitors were barred from manufacturing a similar mirtazapine orally-disintegrating tablet.

43. Finally, in late 1999, Organon began implementing a scheme to defraud Medicaid. Specifically, Organon began marketing to long-term care pharmacies the "opportunity to profit" from Remeron prescriptions under Medicaid, urging these customers to take advantage of a sizable "spread" between the discounted price to pharmacies and the much higher reimbursement to be received by Medicaid. Long-term sales increased steadily with the implementation of this scheme, making Remeron Organon's single largest-selling product even before 2001. In 2001, Organon began to focus on converting Remeron Tablet sales to Remeron SolTab, its patent-protected product, and at that time, the company actually documented its scheme in marketing materials distributed to long-term care pharmacies.

44. Organon's Medicaid scheme was extremely successful. Remeron was Organon's top selling drug from 1999 to 2005. Remeron sales from 1999 to 2004 totaled an estimated $693 million in Medicaid sales, with $347.5 million in long-term care sales. In 2005, Organon's Remeron Medicaid sales totaled about $13 million.

C. Remeron Sales to Long-Term Care

45. Remeron has never been among those anti-depressants that have attained "household name" status such as Prozac, Paxil, or Zoloft. Its selling points—a short half-life and unproven claims of avoidance of side effects such as insomnia and anxiety—had apparently not proved compelling enough to health care providers at large. Remeron, however, has had one, very lucrative niche: *long-term care*. While Remeron products made up only 5% of the overall market share for anti-depressants during the relevant period, they made up 15% percent of anti-depressant sales to long-term care pharmacies—a three-fold increase in market share. From 2000 to 2004, nearly 19% of Remeron's total sales derived from prescriptions for residents of

long-term care facilities. These pharmacies had powerful financial reasons to prefer Remeron, as described below.

i. Pharmaceutical Sales in the Long-Term Care Arena: The Players and the Structures of Sales

46. As Organon noted in its Sales Training Manual for Long Term Care ("LTC Sales Manual"), the senior care marketplace is the fastest-growing segment of the healthcare industry for pharmaceutical sales, as the growing elderly population has created a rapidly rising demand for long-term care services.

47. Most "skilled nursing facilities," or nursing homes, contract with "long-term care pharmacy providers" ("LTCPPs"),[1] which are institutional pharmacies specializing in the skilled nursing facility ("SNF") market. Some nursing homes have their own in-house pharmacies, while many others contract with nationwide corporate pharmacy providers. In 1999, as Organon's LTC Sales Manual explained, the top five corporate long-term care pharmacy providers accounted for over 50% of all U.S. nursing home residents:

Company	Number of SNF Beds Serviced
Omnicare	578,000
PharMerica	380,000
NeighborCare	248,000
NCS	248,000
Living Centers of America	101,000

48. By 2001, according to a Remeron business plan authored by Organon managers John Maddox and Butch McKenna ("Business Plan"), the seven largest LTCPPs accounted for almost 77% of skilled nursing facilities and 72% of total skilled nursing facility beds:

LTCPP	# SNFs	# Beds	# SNFs	# Beds	% SNFs	% Beds

[1] Organon refers to long term care pharmacies such as PharMerica as "pharmacy providers," and thus uses the acronym "LTCPP," but they are also known as "LTCPs," long term care pharmacies.

NeighborCare	2,100	211,500	17,176	1,848,293	12.2%	11.4%
PharMerica	2,850	287,760	17,176	1,848,293	16.6%	15.6%
Omnicare	5,000	495,000	17,176	1,848,293	29.1%	26.8%
NCS	1,875	188,100	17,176	1,848,293	10.9%	10.2%
APS	430	50,000	17,176	1,848,293	2.5%	2.7%
Vencare	325	32,000	17,176	1,848,293	1.9%	1.7%
Sunscript	600	56,800	17,176	1,848,293	3.5%	3.1%
TOTAL	**13,180**	**1,321,160**	**17,176**	**1,848,293**	**76.7%**	**71.5%**

49. In order to buy the drug they disburse to residents, long-term care pharmacies generally contract with one of the following: (1) a long-term care buying group; (2) a group purchasing organization ("GPO"); or (3) the pharmaceutical company itself. Among the most prominent GPOs are Managed Healthcare Associates, Inc. ("MHA"), based in East Hanover, New Jersey, GeriMed, based in Louisville, Kentucky, and Committed Provider Services, an alliance between Bergen Brunswig Drug Company, NCS Healthcare, and Tenet BuyPower. Together, in 2001, these GPOs represented over 90% of Remeron Tablet and Remeron SolTab prescriptions filled in long-term care.

50. Long-term care pharmacies wield a powerful influence over the choice of drugs used in long-term care facilities. Upon entering a nursing home, a resident generally severs his or her ties to a family physician and falls under the care of a physician responsible for the particular facility, who generally visits the facility every thirty days. Nurses and other facility staff who see the patient daily become the physician's influential "eyes and ears," in close consultation with the pharmacy's consultant pharmacist and clinical pharmacy staff. Long-term care pharmacies in turn can implement formularies and "therapeutic interchange programs" to attempt to convert prescriptions to a preferred drug. In its LTC Sales Manual, Organon instructed its LTC sales force that long-term care pharmacy providers work directly with

regional long-term care consultant pharmacists and medical directors to set up such therapeutic interchange and switch programs "in an effort to contain costs and maximize profits."

51. Because long-term care pharmacy providers and GPOs could exert considerable control over the drugs prescribed to nursing home residents, Organon, in marketing drugs in the long-term care arena from 1999 to at least 2004, focused *not on physicians*, but on "key decision-makers" within the long-term care pharmacy providers, such as their regionally-based clinical staff, consultant pharmacists, Directors of Pharmacy Operations, or Purchasing Directors.

52. Organon put it this way in its LTC Sales Manual:

> Field sales personnel have traditionally focused primarily on direct physician interaction. Now, successful sales calls in the long-term care market include other important decision-makers who may influence physician prescribing practices. These include pharmacy provider personnel, consultant pharmacists, nurses, medical directors, and SNF administrators. Your knowledge of the long-term care market and the roles and responsibilities of key decision-makers will give you a competitive advantage.

What pharmacy providers care about, Organon assured its sales force, was a pharmaceutical product's "spread," and its effect on "maximiz[ing] profit." LTC Sales Manual. The "spread" is the difference between the actual selling price and the reimbursement from the state Medicaid programs. "Spread may be a critical component in selecting preferred products within a therapeutic category," Organon noted in its LTC Sales Manual.

53. Beginning in 1999, Organon entrusted the marketing of this spread—and the negotiation of long-term contracts with long-term care pharmacy providers—not to its normal sales force of about 500 Remeron sales representatives, but to a special, more discreet group of about twenty regional account managers specializing in long-term care, called Long Term Care Sales Specialists. In fact, normal field representatives were not permitted to call on long-term care facilities at all.

54. Long-term contracts arising out of this specialized sales force's calls were approved by a contract review committee, which was headed up by the Vice President of Marketing and the Executive Director of Managed Markets, both of whom were members of Organon's Executive Leadership Team.

ii. Long-Term Care Is Dominated by Medicaid, and Organon's Contracts with Long-Term Care Pharmacy Providers and GPOs Reflected Medicaid Pricing.

55. Long-term care residents often arrive at a nursing home with Medicare coverage, but Medicare provides only a limited number of days of coverage. Once those days are exhausted and the resident meets the required income level by depleting his or her savings, that resident becomes eligible for Medicaid, with its accompanying prescription benefit. In the 1999 to 2005 time period, according to Organon, about 86% of nursing home residents were Medicaid-eligible, including those eligible under both Medicare and Medicaid. In contrast, managed care and cash reimbursement in 1997 comprised only 14% of total long-term care revenue.

56. Medicaid thus dominated the long-term care segment of pharmaceutical sales until Medicare Part D commenced in January of 2006. Exploiting Medicaid reimbursement rules played a central role in how Organon did business in that arena. Specifically, as described in more detail below, from 1999 to at least 2005, Organon offered significant rebates, coupled with an inflated Average Wholesale Price ("AWP") for Remeron Tablet and Remeron SolTab in order to create additional profit for pharmacies prescribing Remeron Tablet and Remeron SolTab. AWP is the price at which a pharmaceutical manufacturer or a wholesaler typically sells a drug to a retail customer. Organon then marketed that spread to large corporate long-term care pharmacy providers and buying groups and entered long-term contracts providing specifically

for those discounts, rebates, and other financial incentives, often in exchange for bestowing Remeron Tablet and Remeron SolTab with a "preferred" status. All of these spread enhancements were done at Medicaid's expense.

57. Relators' evidence of this Medicaid scheme is abundant: Organon compiled a notebook entitled "Remeron SolTab Therapeutic Interchange Toolkit," accompanied by branded PowerPoint presentation and financial modeling tools meant to calculate to what extent long-term care pharmacy providers could enrich themselves by increasing the number of Remeron scripts they filled. That notebook is described in more detail below.

VIII. ORGANON'S SCHEME TO DEFRAUD MEDICAID THROUGH FRAUDULENT INFLATION OF AWP, MARKETING THE SPREAD AND FAILING TO REPORT BEST PRICE

A. Drug Reimbursement Under State Medicaid Programs

i. Medicaid Reimbursement Formulas

58. Reimbursement for drugs under state Medicaid programs depends in part on whether the drug is a single source or multiple source drug. A single source drug means a drug that is produced or distributed under an original new drug application approved by the FDA. 42 U.S.C. § 1396r-8(k)(7)(iv). A multiple source or multi-source drug is one for which there is at least one other drug product that is rated therapeutically equivalent or pharmaceutically equivalent and bioequivalent under FDA standards and is sold or marketed in the states. 42 U.S.C. § 1396r-8(k)(i).

59. When paying claims for reimbursement of drugs, the state Medicaid programs' goal has been to pay an amount which, in the aggregate, reflects the lower of: (1) the estimated acquisition cost ("EAC") of covered drugs, plus a reasonable dispensing fee; or (2) a provider's usual and customary charge to the general public. To determine the EAC for a covered drug,

state Medicaid programs are required to develop reimbursement formulas that must be approved by the Secretary of Health and Human Services ("HHS"). 42 C.F.R. §§ 447.331, 447.332, 447.333 (2005).

60. While specific reimbursement formulas vary from state to state, the various state Medicaid programs generally have reimbursed for each drug based on the lowest of: (a) the EAC as set by the states; (b) the maximum allowable cost ("MAC") set by the state Pharmaceutical Boards of the Federal Upper Limit ("FUL") set by the federal government; or (c) the providers' usual and customary charge. For multiple source drugs subject to a federal upper limit, states must, in the aggregate, not pay more than those limits. 42 C.F.R. §§ 447.331, 447.332, 447.333 (2005).

a. States' Methods for Calculating Estimated Acquisition Cost

61. The states' various methodologies for arriving at EAC include:

(a) discounting a percentage off of the Average Wholesale Price ("AWP");

(b) adding a percentage to the Wholesale Acquisition Cost ("WAC"); and/or

(c) requiring the drug companies to certify prices directly in writing to the Medicaid program in response to state requests for particular pricing information.

62. AWP is used to refer to the price at which a pharmaceutical manufacturer or a wholesaler typically sells a drug to a retail customer, who then administers it to a patient. WAC is used to refer to the price at which a pharmaceutical manufacturer typically sells a drug to wholesalers, who then resell it to a retail customer.

63. While the majority of states use published AWPs to calculate reimbursement, nine states (Alabama, Arkansas, Colorado, Florida, Maryland, Massachusetts, Ohio, Rhode Island, and Texas) use the wholesale acquisition cost ("WAC") to set the EAC.

64. The AWPs and WACs relied upon by the state Medicaid programs are published for each drug identified by National Drug Code ("NDC"). There are several pharmaceutical industry compendia that periodically publish, in printed and electronic media, the AWPs for the tens of thousands of drugs. These compendia have generally been published by: (1) Thompson Publishing, publisher of the *Red Book* and various other price publications; (2) First Databank, publisher of the *Blue Book* and other electronic price publications; or (3) Medi-Span, Inc., publisher of an electronic or automated price service and the Hospital Formulary Pricing guide. Thompson Publishing, First Databank and Medi-Span, Inc. are hereafter referred to as the "Publishers" and their various publications and data services are hereinafter referred to as "Price Publications."

65. In periodically announcing the AWP and WAC for each drug, the Publishers publish the prices that are supplied to them by pharmaceutical manufacturers for their respective drugs. The forward to the 1999 edition of the *Red Book* states that "all pricing information is supplied and verified by the products manufacturers, and it should be noted that no independent review of those prices for accuracy is conducted." A June 1996 Dow Jones news article reported that Phil Southerd, an associate product manager of the *Red Book*, stated that it only publishes prices that are faxed directly from the manufacturer. Thus, the AWP and WAC generally are not independently determined by the Publishers. The pharmaceutical manufacturers control the prices listed as the AWPs and WACs for each drug.

66. The Medicaid system, which bases its reimbursement rates for drugs on the published AWP and WAC, is thus dependent on the honesty of the drug manufacturers.

67. Settlements and extensive and ongoing federal and Congressional investigations have revealed that numerous pharmaceutical manufacturers have engaged in a scheme involving the fraudulent reporting of the AWPs for certain prescription pharmaceuticals including, but not limited to, prescription pharmaceuticals covered by Medicaid.

b. Multi-Source Drug Reimbursement

68. States use either maximum allowable cost ("MAC") or the federal upper limit ("FUL") to determine Medicaid reimbursement for multiple source drugs. States with a MAC system either use the lowest AWP for a generic version of the drug or their own formulas to determine MAC. States with MAC programs generally publish lists of generic and multi-source drugs along with the maximum price at which Medicaid will reimburse. In general, the prices on the MAC lists are lower than the FUL prices set by the federal government.

69. Some states instead rely on the FULs to set reimbursement for multiple source drugs. The federal government sets FUL on multiple source drugs that are available from at least three suppliers and for which all formulations of the drug are therapeutically or pharmaceutically equivalent. 42 U.S.C. § 1396r-8(e)(4); 42 C.F.R. § 447.332(a). The FUL is set at 150% of the published price for the least costly therapeutic equivalent. 42 C.F.R. § 447.332(b).

c. Other State Methods for Setting Medicaid Reimbursement Rate for Drugs

70. In addition to relying on the manufacturers' reported prices as published in the Price Publications or on MAC or FUL for multi-source drugs, some state Medicaid programs also received price representations directly from manufacturers, and relied on these

representations to confirm the accuracy of the figures they use to determine state reimbursement amounts. For example, the State of Texas requires drug companies to submit their prices directly to the Texas Medicaid program in a signed certification attesting to the accuracy of the price information.

ii. "Best Price" Requirements

71. Under 42 U.S.C. § 1396r-8, in order for a manufacturer of a drug to have its products compensated under Medicaid, the manufacturer must enter into a rebate agreement with the Secretary of HHS. In Medicaid's multi-layered statutory system, even after Medicaid reimburses a pharmacy or provider for a prescription drug, it expects a quarterly accounting from the drug's manufacturer to ensure that it has received the "best price" for the drug industry-wide, and that the manufacturer pays a rebate for any shortfall.

a. Meaning of "Average Manufacturer Price" and "Best Price"

72. Organon entered into a rebate agreement with Medicaid, under which Organon had to comply with the rebate requirements set forth in 42 U.S.C. § 1396r-8, including reporting its "average manufacturer price" ("AMP") and "best price" for each of its drugs to Centers for Medicare and Medicaid Services ("CMS") each quarter. AMP and best price are used to calculate the quarterly rebate payment that each participating manufacturer must make to state Medicaid pharmacy programs. The AMP is defined as "the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade, after deducting customary prompt pay discounts." 42 U.S.C. § 1396r-8(k)(1). Discounts and rebates provided to long-term care pharmacy providers were a customary deduction from AMP during the relevant time period.

73. The Medicaid statute defines "best price" as "the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity or governmental entity." 42 U.S.C. § 1396r-8(c)(1)(C). The section also provides that "best price" includes "cash discounts, free goods that are contingent on any purchase requirement, volume discounts and rebates."

74. Best price does not include "prices that are merely nominal in amount" unless those nominal priced sales are contingent upon any purchase requirement. 42 U.S.C. § 1396r-8(c)(1)(C)(ii). In addition, prices offered to 340B covered entities are not included in the best price calculation. 42 U.S.C. § 139r-8(c)(1)(C)(i). To assure that prices offered to 340B covered entities are not included in the rebate calculation, the Office of Pharmacy Affairs ("OPA") for Department of Health and Human Services maintains a "Medicaid Exclusion" file, which lists the current eligible 340B entities that have reported their intent to fill Medicaid prescriptions with 340B-purchased drugs. The "Medicaid Exclusion" file allows state Medicaid agencies to determine which 340B entities' claims must be excluded for rebate requests from a drug manufacturer. Drug manufacturers also maintain 340B membership lists that track entities eligible to receive 340B pricing; these lists are generally updated on a quarterly basis.

b. Calculation of Medicaid Rebate

75. The amount of the rebate to the state Medicaid programs is calculated in three steps. First, the basic rebate is determined. The basic rebate is equal to the greater of AMP multiplied by 15.1% or AMP minus best price.

76. Second, once the basic rebate has been calculated, any additional rebates are calculated by comparing the current quarter AMP to the baseline AMP. The baseline AMP is defined as the AMP at the time of launch. The difference between the current quarter AMP and

the baseline AMP is compared to the Consumer Price Index ("CPI") to determine if the AMP rose at a rate higher than the prevailing CPI. The CPI represents changes in prices of all goods and services purchased for consumption by urban households. If the current quarter AMP exceeds the baseline AMP plus the CPI, the excess amount becomes the additional rebate. If the current quarter AMP is equal to or less than the baseline AMP plus the CPI, there is no additional rebate.

77. Finally, a calculation is performed for the unit rebate amount ("URA") for each NDC of a covered drug. The basic rebate is added to the additional rebate, and then the rebates are divided by the per unit amount of the drug. The resulting number is the URA, which is multiplied by the number of units dispensed to Medicaid recipients under each state participating program.

B. Organon's Schemes to Defraud Medicaid

i. Overview of the Schemes

78. From 1999 through 2005, Organon engaged in a fraudulent scheme designed to exploit the Medicaid reimbursement system by offering profits based on the spread and by offering deep discounts to further increase the spread in exchange for prescriptions for Remeron Tablet and Remeron SolTab at the expense of the state Medicaid programs. Knowing that state Medicaid programs relied on Organon's reported prices in the price reporting compendia to set their reimbursement rates for Remeron Tablet and Remeron SolTab, Organon reported inflated AWPs for Remeron Tablet and Remeron SolTab.

79. Organon then increased and marketed this spread by offering deep discounts and rebates to its GPO and individual long-term care pharmacy provider customers. Organon conspired with its customers to increase this spread by entering into long-term contracts with

provisions offering excessive and illegal discounts and rebates. These contracts offered a ramp-up discount period whereby the highest levels of discounts were offered temporarily without meeting any market share or volume criteria. This ramp-up discount period started in February of 1999 and was intended to run only through June 1999; through various amendments, however, this ramp-up period was extended for years until it ultimately expired in December 31, 2005. All of these spread enhancements were at Medicaid's expense.

80. Organon's scheme succeeded precisely because providers were able to obtain Remeron Tablet and Remeron SolTab at prices significantly below Medicaid reimbursement levels. The widely-available prices from wholesalers and through GPO agreements for Remeron Tablet and Remeron SolTab drugs were considerably less than the WAC and 44% to 48% less than the reported AWP used to establish the Medicaid reimbursement.

81. Further, Organon's scheme to have its sales representatives fraudulently market Remeron and Remeron SolTab's spread ultimately impacted Organon's reported quarterly AMP calculations. Under the rebate agreement, Organon was required to calculate its AMP by averaging its actual prices for Remeron Tablet and Remeron SolTab. In making this calculation, Organon made sure to deduct the deep discounts and rebates that it illegally offered to long-term care pharmacy providers on these drugs. Doing so produced a lower AMP than if the discounts had not been considered. Under the formula used to calculate a pharmaceutical manufacturer's rebate liability, a reduced AMP results in a lower rebate amount due Medicaid.[2] Organon therefore decreased its liability under its rebate agreement with Medicaid by including illegally-discounted long-term care discounts and rebates into its calculation of AMP.

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[2] A reduced AMP does not, however, affect in any way Medicaid's determination of reimbursement amount for a prescription. In no way, therefore, did calculating a lower AMP constitute a reporting of the discounts to Medicaid. Nor would Medicaid have had any knowledge of the illegal discounts based on this reporting.

82. In addition, Organon avoided reporting its true best price for Remeron Tablet and Remeron SolTab. For example, in at least two instances, one involving Omnicare and one involving PharMerica, and product with a short-shelf life, Organon avoided disclosing the true best price by coupling the sale of nominally-priced Remeron SolTab with the requirement to purchase a similar quantity at normal commercial prices.

83. Organon fraudulently violated its Medicaid rebate agreement in a further respect, by failing to maintain adequate procedures and control of its membership list of 340B covered entities to whom Organon must offer 340B pricing on all its drugs, including Remeron and Remeron SolTab. 340B sales transactions are exempt from best price determination, to the extent that these government prices are only extended to 340B eligible entities. Organon was advised of these issues but elected not resolve the matter. Organon understood that not including such transactions in its reported "best price" calculation, would grossly lower their Medicaid rebate liability.

ii. Organon Marketed the "Spread" and Offered Deep Discounts and Other Financial Inducements to Pharmacy Providers

84. Until 1999, Organon negotiated only modest discounts with GPOs–2% to 3% administrative fees paid to the GPO based on members' Remeron purchases, in exchange for promoting the drug to members. These discounts fell under a limited Anti-Kickback Statute exemption for small, fixed GPO discounts. *See* 42 U.S.C. § 1320a-7b(b)(3); 42 C.F.R. § 1001.952(j).

85. Similarly, Organon negotiated contracts for discounted Remeron with major individual long-term care pharmacy providers, but offered only modest discounts. While Relators have found pre-1999 Remeron pricing contracts to be scarce, at least one contract